Clinical Edit Criteria Proposal

Drug/Drug Class:	**Narcolepsy Inhibitors Clinical Edit**
Date:	**February 26, 2014**
Prepared for:	
Prepared by:	**MO HealthNet**

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose: To ensure appropriate utilization and control of Provigil® (Modafinil tablets), Nuvigil® (Armodafinil tablets) and Xyrem (Sodium Oxybate solution).

Why was this Issue Selected:

Provigil® and Nuvigil® are branded drug products indicated to improve wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea, narcolepsy and shift work disorder. Xyrem® is a branded drug product indicated for excessive daytime sleepiness and cataplexy in patients with narcolepsy. Narcolepsy is not rare, but it is an under recognized and underdiagnosed condition. The disorder is estimated to affect about one in every 2,000 Americans, but the exact prevalence rate remains uncertain and the disorder may affect a larger segment of the population. Narcolepsy appears throughout the world in every racial and ethnic group, affecting males and females equally, but prevalence rates vary among populations. Compared to the U.S. Population, for example, the prevalence rate is substantially lower in Israel (about one per 500,000) and considerably higher in Japan (about one per 600). Sleep apnea is very common, as common as adult diabetes, and affects more than twelve million Americans, according to the National Institutes of Health. Obstructive sleep apnea (OSA) is caused by a blockage of the airway, usually when the soft tissue in the rear of the throat collapses and closes during sleep. With each apnea event, the brain briefly arouses people with sleep apnea in order for them to resume breathing, but consequently sleep is extremely fragmented and of poor quality. Millions of Americans are shift work employees and if their shift hours change frequently a shift work sleep disorder may develop. The number of Americans with a shift work sleep disorder has not been determined. All three of these sleep disorders can lead to serious consequences if not treated.

Program-specific information:

Drug	Claims	Costs
Provigil 100 mg tablets	186	$160,655*
Provigil 200 mg tablets	834	$897,726*
Nuvigil 50 mg tablets	74	$15,584*
Nuvigil 150 mg tablets	451	$229,978*
Nuvigil 250 mg tablets	623	$300,381*
Xyrem 500 mg/mL solution	167	$644,795**
Totals	2,335	$2,249,119

*July 1, 2012 – June 30, 2013 - FFS Claims
** January 1, 2012 – December 31, 2012 – FFS Claims

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Non-Preferred Agent** ☒ **Appropriate Indications** ☐ **Other:**

Data Sources: ☐ **Only administrative databases** ☒ **Databases + Prescriber-supplied**

Setting & Population

- Age range: Modafinil age ≥ 16yo, Armodafinil age ≥ 17yo, and Sodium Oxybate age ≥ 18yo
- Gender: males and females

Approval Criteria

Modafinil and Armodafinil

- Appropriate Diagnosis in the past 2 years
  - Narcolepsy (ICD-9 347.0; ICD-10 G47.4)
  - Obstructive sleep apnea (ICD-9 327.23; ICD-10 G47.33)
    - With history of CPAP
  - Shift work disorder (ICD-9 327.36 ICD-10 G47.26)
  - Hypersomnia (ICD-9 780.53 and 780.54; ICD-10 G47.10-G47.19)
  - Fatigue related to multiple sclerosis (ICD-9 340; ICD-10 G35)
    - With adequate trial of amantadine in past year
- Trial and failure of a stimulant
- Documented compliance on current therapy regimen

Sodium Oxybate

- Diagnosis of narcolepsy with cataplexy (ICD-9 347.01; ICD-10 G47.411, G47.421) **and**
- Trial and failure of Provigil or Nuvigil
- Documented compliance on current therapy regimen

Denial Criteria

Modafinil and Armodafinil

- Claims for patients under 16 years of age for modafinil and <17 years of age for armodafinil (require clinical consultant review)
- Patients do not meet approval criteria
- Dosage exceeds FDA limitation
  - o modafinil 400 mg/day
  - o armodafinil 250 mg/day

Sodium Oxybate

- Claims for patients under 18 years of age
- Patients do not meet approval criteria
- History of Substance Abuse
- History of renal impairment
- History of heart failure
- Uncontrolled hypertension
- History of suicide attempt
- Dosage exceeds FDA limit of 9 Grams/day

Required Documentation

Laboratory results:	☒	Progress notes:	☐
MedWatch form:	☐		☐

Appendix A

Drug	Unit Limit Per Day
Provigil 100 mg tablets	2
Provigil 200 mg tablets	2
Nuvigil 50 mg tablets	1
Nuvigil 150 mg tablets	1
Nuvigil 250 mg tablets	1
Xyrem 500 mg/mL solution	18

References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2010.
2. Facts and Comparisons; 2010.
3. Package Insert for Provigil, Cephalon, Inc., Frazier, PA 19355; 2010
4. Package Insert for Nuvigil, Cephalon, Inc., Frazier, PA 19355; 2010
5. USPDI, Micromedex, 2010.
6. Package Insert for Xyrem, Jazz Pharmaceuticals, Inc., Philadelphia, PA 19103; 2012